FALL 2017

Maryland Board of Pharmacy Hereight Street Street

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The Mission of the Maryland Board of Pharmacy is to protect Maryland consumers and to promote quality health care in the field of pharmacy through licensing pharmacists and registering pharmacy technicians and student interns, issuing permits to pharmacies and distributors, setting pharmacy practice standards and through developing and enforcing regulations and legislation, resolving complaints, and educating the public.

The Maryland Board of Pharmacy 4201 Patterson Avenue Baltimore, Maryland 21215 Tel: 410-764-4755 Fax: 410-358-6207 Toll Free: 800-542-4964 TTYL BALTO-383-7555



FROM THE EXECUTIVE DIRECTOR'S DESK --- Deena Speights-Napata

2017—What A Year! And it's not over yet.....

As the end of CY 2017 fast approaches, it seems like a good time to reflect on our achievements this year. We have been involved in many different aspects of public health, fulfilling our mission and vision of protecting the public and setting a standard for pharmaceutical services that ensure safety and quality health care for our citizens. We've worked toward achieving our mission and vision primarily through being responsive to the public through our call center and customer service initiative, through establishing internal and external collaborations, continuing to be on the cutting edge of information technology development, and working with others on legislative initiatives and regulatory development.

For example, let's take a look at the call center and customer service initiative. The board this calendar year, based on year to date numbers, is projected to respond to over 20,000 Inquiries and Data requests from Pharmacists and Stakeholders, including public and licensee inquiries (phone calls, faxes, and emails) WOW!!!

Other areas of significant achievement include:

Information/Technology Development

- An electronic Distributor application was developed to ensure an easy distributor application process.
- An electronic inspection form was developed which cut by 50% the time needed to conduct and document an inspection
- Development of Fraud Detection protocol to increase efforts at protecting personal identifier information of licensees

Board of Pharmacy Collaborations

- Montgomery County Office of Legislative Affairs
- MDH new centralized licensing system discussion
- Maryland Governor's Opioid Operational Command Center member
- UMES and Howard University pharmacy student presentations
- Internship/preceptor agreement with UMES established

- University of Baltimore Law School internship agreement in progress
- Participation in the National Boards of Pharmacy Task Force on the Definition of a Patient-Pharmacist Relationship
- Participation in the Pharmacy Technician Certification board conference on technician certification requirements
- Maryland Society of Health-System Pharmacy member
- Maryland Office of Controlled Substances Administration
- Maryland Medicaid
- MDH Career Day
- MDH Office of Infectious Disease in promotion of syringe sales in pharmacies
- DEA Annual Drug Take Back Day promotion
- Regional Opioid 7 Substance Abuse Summit—Meeting with Washington DC, Virginia, and MD opioid epidemic strategists
- National boards of pharmacy annual regional and national meetings
- USP 800 Director of Compliance certification
- Maryland Hospital Association—Naloxone Prescribing and Dispensing and Hospital Role in Addressing The Opioid Crises, Overdose Survivors Outreach Project, and Alcohol and Drug Use Screening webinar series
- Pharmacists Prescribing Contraceptives Workgroup
- Maryland Behavioral Health Administration, Prescription Drug Monitoring Program
- East Coast Regional Controlled Substances Coalition
- FDA Annual meeting

Procurements

- Software engineering contract to develop and monitor digital inspection form
- New Rehabilitation Committee contract developed and posted for bid. The new contract expands the scope of work, increases funding, and extends the term of service to up to 5 years.

Staffing

- Call Center Director position created to oversee the call center, licensing data input, supports staff operations, and customer service
- Inspection and Investigative staff received nationally recognized CLEAR basic and advanced certification
- Naloxone Administration certification training for Board of Pharmacy staff
- NABP Sterile Compounding Certification for Inspection Supervisor

Legislation and Regulation

- Facilitator of Maryland Contraceptive Work group regulation development
- Investigational Drugs, Biological Products, and Devices Right to Try Act
- Licensed Pharmacists Risks of Opioid Addiction Notifications
- State Board of Pharmacy Registered Pharmacy Technicians Exemption for Pharmacy Students

- Oncologists Dispensing and Insurance Coverage of Orally Administered Cancer Chemotherapy
- Health Care Providers Opioid Prescriptions Limitations and Requirements
- Pharmacists Administration of the Influenza Vaccination Age Requirement
- Pharmacists Substitution and Dispensing of Biological Products
- Courts Criminal and Civil Immunity Prescribing, Dispensing, and Administering Opioid Antagonists
- Public Health Expedited Partner Therapy Trichomoniasis and Pharmacist Dispensing
- Health Insurance Specialty Drugs Authority to Dispense
- Health Insurance Prescription Drugs Dispensing Synchronization

Events

- Annual Continuing Education Breakfast—Record number of over 300 pharmacists receiving continuing education credits
- Annul reception for departing board commissioners
- Annual staff appreciation luncheon

And just in case you don't know, all of the folks who make these achievements possible include the fabulous commissioners and legal counsel on the Board, as well as the amazing staff of Board professionals with whom I work. Combined, these are the people who make it a pleasure for me to come to work every day. They include:

BOARD:

Mitra Gavgani, Board President, Home Infusion Representative	Jennifer L. Hardesty, Long Term Care Representative
Zeno W. St. Cyr II, Secretary, Consumer Representative	Neil B. Leikach, Independent Representative
•	Brenda Oliver, Consumer Representative
Kevin Morgan, Treasurer,	
Chain Drug Store Representative	Roderick Peters, Independent Pharmacist Representative
Daniel M. Ashby, Acute Care Hospital	•
Representative	Rhonda M. Toney, At-Large Representative
Efstratios (Steve) Bouyoukas, Chain Drug Store Representative	Ellen H. Yankellow, At-Large Representative
•	Linda Bethman, Board Counsel
Karla Evans, Acute Care Hospital Representative	Brett Felter, Board Counsel

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STAFF:

Edward Fields Deputy Director and Operations Manager

Jacqueline Green, Database Manager Janey Partin, Web Design/Computer Network Specialist Trainee

Tom Evans, Director of Compliance

Etzion Brand, Licensing Manager

Jered Pasay, Laboratory Scientist
Lisa Sanderoff, Investigator Supervisor
Jada Collins, Acting Health Occupations
Investigator
Sandra Kracke, Investigator
Heather McLaughlin, Compliance Coordinator
Shiela West, Investigator
Nancy Richard, Acting Inspector Supervisor
Amanda Barefield, Inspector
Cheryl Johnson, Inspector
Emory Lin, Inspector
Kerri Weigley, Inspector
Shanelle Young, Inspector

Darchelle, Lanteon-Edmonds, Licensing Specialist
Lead
Christopher Ayers, Licensing Specialist
Doris James, Licensing Specialist
Keisha Wise, Licensing Specialist

Brian Logan, Legislation & Regulations
Coordinator

Andrew Siske, Legislative Intern

Nakia Jordan, Call Center/Data Input & Analysis Manager

Christine Chew, Management Associate, Staff Lead
Rhonda Goodman, Call Center Staff Lead and
Customer Service Specialist
John Burnham, Customer Service Specialist
Kimberley Goodman, Customer Service Specialist
Leroy Jackson, Customer Service Specialist
Joy Lane, Customer Specialist
Lawrence Tates, Customer Service Specialist
Janet Seeds, Public Information/Education/
Communication/Training Coordinator

I'm looking forward to 2018 as another great year of outstanding achievement!

RECOGNITION DINNER at Radisson Hotel at Cross Keys on October 18, 2017

Past Board Commissioners along with previous Staff Member were recognized for their service and were awarded with Governor's Citations and gifts.

Charmaine Rochester-Eyeguokan, PharmD, CDE, BCPS, BCACP served as an At-Large Board Representative from 4/2013 through 4/2017 and was represented on numerous committees. Bruce L. Zagnit, BS of Pharmacy served as an Independent Board Representative and served as the Chair of the Public Relations Committee from 4/2013 through 4/2017. Sajal Roy, PharmD, CPG, CPSO, CACP, CSP, served as an Acute Care Hospital Board Representative from 4/2013 through 4/2017 and was Chair of the Emergency



Preparedness Task Force. *Trinita Robinson* served as Board Consumer Representative and was represented on numerous Board committees from 4/2013 through 4/2017.

CONTINUING EDUCATION BREAKFAST

Janet Seeds, Public Information/Education/Communication/Training Coordinator



Close to two hundred and fifty people entered the Maritime Conference Center to participate in the Maryland Board of Pharmacy's Continuing Education Breakfast on Sunday, October 22, 2017. Breakfast was served in the cafeteria, registration was taken, and then participants made the short walk over to the auditorium to begin their morning of training. How Medical Marijuana and Opioids Impact Pharmacy was the title of this event. Board

President, Mitra Gavgani and Public Relations Chairman, Ellen Yankellow, welcomed all attendees and introduced the speakers.

The first speaker, Deborah Miran, from D. Miran Consulting. Deborah is a former commissioner on the Maryland Medical Cannabis Commission. The title of her educational segment as, "Regulations and Protocols: What's Happening Now." She identified the current status of the Maryland cannabis program with an update on regulations, dispensaries, patient, and provider rules. She taught the attendees to be able to identify various routes of administration and dosage forms of medical cannabis. Ms. Miran's perspective was based on her thirty years of experience in the US pharmaceutical industry.



The second speaker, Dr. David Gorelick, MD, PhD, DLFAPA. Dr. Gorelick is a part-time Professor of Psychiatry



at the University of Maryland, having retired from the Intramural Research Program of the National Institute on Drug Abuse (NIDA), US National Institutes of Health (NIH) in Baltimore, MD. He explained the Maryland medical cannabis program as he believed it relates to the pharmacy profession. He identified and explained scientific evidence supporting the medical use of cannabis for indications under the Maryland medical cannabis program. Dr. Gorelick also identified commonly prescribed medications that might have clinically significant interactions

with Medical cannabis. His segment was entitled, "Medical Marijuana Uses and Drug Interactions."

Three pharmacists were honored this for having been licensed for 60 continuous years. Board President, Mitra Gavgani, and Executive Director, Deena Speights-Napata, were privileged to bestow Governor's Citations upon the two honorees who were in attendance. Norman L. Levin and Arnold L. Davidov said a few words;



in fact, Dr. Levin read a poem that brought the house down. Dr. Davidov, in turn, stated that he owed his career to Dr. Levin. A Governor's Citation will be mailed to Dr. Herman Glassband who could not attend this event. The Maryland Board of Pharmacy would like to thank each of these gentlemen for their years of service to the citizens of Maryland.

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After the recognition ceremony, Darren Weiss, JD, presented the, "Legal Aspects of Medical Marijuana." He identified the legal, business, and ethical considerations for pharmacists around the topic of medical cannabis. Mr. Weiss described the medical cannabis enforcement priorities, and he outlined the development and structure of Maryland's Medical Cannabis Market. The audience exploded with questions for Mr. Weiss and the facilitator had to cut the questions off in order to continue with the rest of the program.

At this time, Maryland Department of Health Secretary, Dennis Schrader, greeted the pharmacists and technicians who were in attendance. Secretary Schrader spoke briefly concerning the opioid crisis in Maryland. He stated that he wished to continue the dialogue between the Board and his office. He thank pharmacist, technicians and other health professionals for their role in combatting the opioid crisis.





The final presenter for the day was Dr. G. Caleb Alexander, MD, MS, from Johns Hopkins Bloomberg School of Public Health. He is an Associate

Professor of Epidemiology and Medicine. Even though the morning had already been filled with much information, participants seemed to be extremely attentive to his session, "Prescribing and Dispensing Opioids." He had so much important information to share as he changed gears from what had previously been discussed all morning. He reviewed the historical underpinnings of the opioid epidemic, explored key clinical and policy solutions that are being considered for

implementation, critically evaluated some proposed risk mitigation measures, dispelled myths that delayed progress in reducing opioid-related injuries and deaths, and identified important unanswered questions that remain.

The audience remained engaged with many questions for the speakers. The Maryland Board of Pharmacy looks forward to many more continuing education events and hopes to share them with you.

MARYLAND HEALTH DEPARTMENT CAREER DAY

The Maryland Board of Pharmacy (Board) participated in the Maryland Department of Health Career Day held on October 19, 2017 at 201 W. Preston Street, Baltimore, MD. This was a great opportunity for people to find out more about the Board and to explore if this would be a place they would enjoy working. An on-going video was displayed, informational brochures were distributed, and medicine safety tips were handed out.

INTRODUCING THE NEWEST BOARD STAFF MEMBERS...

Andrew Siske is a law student at the University of Baltimore and is working as a Legislative and Regulatory Intern.

Jered Pasay is our new Laboratory Scientist and comes to us from Johns Hopkins Medical Institute, having been there for 11 years.

Refrigerators and Freezers in Pharmacies

Rhonda Toney, Board Commissioner

According to COMAR 10.34.07.01-1 pharmacies shall have a refrigerator that is used solely for the storage of drugs that require refrigeration with a thermometer or a temperature monitoring device. A freezer shall be utilized if the pharmacy stocks medications that are required to be frozen with a thermometer or temperature monitoring device.

The Center for Disease Control (CDC) recommends the following best practices for refrigerated and frozen vaccines. Staff should unpack vaccines immediately when received by the distributor and rotate stock to ensure that vaccines due to expire are used in a timely manner. Vaccines should be kept in the original boxes with lids closed to prevent exposure from light. Dormitory style refrigerator/ freezers are NOT recommended for vaccine storage under any circumstance, even temporarily due to consistently unacceptable performance of these refrigerators. Food and drinks should never be stored in a refrigerator/freezer that is used to store pharmacy medications. Vaccines should not be stored in the doors of the unit. It is recommended that pharmacy staff post a "do not unplug" sign by the electrical outlet. Air vents for refrigerators and freezers should not be blocked. Temperature monitoring of the storage unit should be logged at least 2 times each work day. Temperatures that are out of range should be reported to management immediately. The top shelf of the refrigerator should not be used for vaccine storage.

The following temperature ranges are considered acceptable. Refrigerated vaccinations should be stored at a range of 34-46 degrees F. The ideal

temperature range for frozen vaccines is -58 degrees Fahrenheit to 5 degrees Fahrenheit.

Before an emergency arises such as equipment failure, power outage, or a natural disaster, pharmacy management and staff should be prepared with an emergency plan that includes steps to take to protect vaccine inventory. If an emergency event occurs, pharmacy staff should activate the emergency plan immediately.

As part of a pharmacy's annual inspection, Board of Pharmacy inspectors will verify that medication refrigerator(s) contain only prescriptions items. The inspector will also verify that medication refrigerator(s) have a thermometer and the current temperature is between (36-46F). If the pharmacy stocks medications requiring freezing, the freezer will be checked to verify it is maintained at temperatures required by the medications stored within it.

If an inspector finds that a pharmacy has not complied with regulatory requirements, it will be noted in the inspection report and forwarded to the Board for review and possible further action. Pharmacists and technicians should maintain the safety and integrity of medications by preventing food and beverages from being stored in the pharmacy medication refrigerator and freezer.

For additional information on vaccine storage, guidelines and recommendations, and packing vaccines for transport during an emergency situation, go to: https://www.cdc.gov/vaccines/hcp/admin/storage/index.html

References:

Vaccine Storage and Handling." Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 23 March 2017,www.ece.gov/vaccines/hep/admin/storage/index.html.

Maryland Pharmacy Laws (2017 ed.) Code of Maryland Regulations, Matthew Bender and Company, Inc.

https://health.maryland.gov/pharmacy/does/BOPForms/Community%20Inspection%Form.pdf



NABP National Pharmacy Compliance News



Reprinted from the National Association of Boards of Pharmacy FOUNDATION

Pharmacy Domain Signals Safety on the Web

With only 4% of websites selling prescription drugs online following United States pharmacy laws and practice standards, consumers seeking medications online are faced with the daunting task of finding a safe site. To assist consumers and those legitimate pharmacies with an online presence, NABP has streamlined its website verification programs. As of September 1, 2017, NABP is only offering the .Pharmacy Verified Websites Program and the Verified Internet Pharmacy Practice Sites® (VIPPS®) program, providing an easy choice for safety-minded consumers and pharmacies alike. The .Pharmacy Program, which was launched in 2014, enables qualified pharmacies and pharmacy-related businesses to register a web address with the .pharmacy domain. A .pharmacy domain (pronounced "dot pharmacy") is part of a website's address like ".com" or ".biz": www.safe.pharmacy. It enables people to identify an online pharmacy or pharmacy-related website as safe and legitimate. Since .pharmacy is a verified domain, websites are evaluated against a set of safety standards before an applicant is approved to register the domain.

In addition to showing patients that they operate a safe website, the .pharmacy domain allows pharmacies and related entities to advertise online through Google, Bing, and Yahoo! The .Pharmacy Program replaces the e-Advertiser Approval^{CM} and Veterinary-VIPPS® programs for those entities that are not eligible to apply for VIPPS but want to advertise with the search engines.

For more information about the .Pharmacy Program, including the application and domain name registration process and fees, visit www.safe.pharmacy/apply.

Quality Processes, Risk Management, and Culture: HR-Related Policies That Conflict With a Just Culture

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at www.ismp.org. Email: ismpinfo@ismp.org.

As health care organizations move toward a "Just Culture," one of the areas potentially overlooked is human resource (HR)-related policies and procedures. Because these policies and procedures typically describe staff expectations, individual accountability, and disciplinary processes, they must be reviewed and often revised to ensure alignment with the tenets of a Just Culture. Otherwise, the journey will be long and unsuccessful if the policies are in conflict with a Just Culture.

In a Just Culture, HR-related policies and procedures regarding safety should hold all individuals equally accountable for the quality of their behavioral choices and should not focus on errors (which are not a behavioral choice), except for the expectation to report

them. Policies and procedures should reflect a tone that is proactive toward risk identification, rather than reactive to errors and adverse outcomes. They should define human error as inadvertent, with a response of consoling individuals and conducting an investigation to determine how to redesign systems to prevent errors or detect them before reaching the patient. Policies and procedures should describe how to investigate a procedural violation to determine its causes and scope, and how to coach staff who have engaged in atrisk behaviors under the mistaken, but good faith, belief that the risks were insignificant or justified. For outcome-based duties related to a business code of conduct, such as arriving to work on time and wearing identification badges, policies should be clear about expectations and the actions that will be taken when they are not met. When describing reckless behavior (actions involving a conscious disregard of what an individual knows is a substantial and unjustifiable risk), remove any reference to "negligent" or "criminal" conduct as the basis for disciplinary action. Regrettably, mere human error can result in legal action (criminal negligence), but human error is never reckless behavior. Also ensure that event reporting and investigation policies and procedures support the tenets of a Just Culture.

While HR-related policies and procedures cannot guarantee that the desired actions will be realized in practice, they are a critical step for building an organizational foundation for success. Old punitive policies risk slipping back into an unjust culture. As organizations align actual practice with a Just Culture, they also need to align supporting policies and procedures.

AMA Task Force to Reduce Opioid Abuse Promotes Safe Storage, Disposal of Opioids

The American Medical Association (AMA) Task Force to Reduce Opioid Abuse released a resource document that urges physicians and other health care providers to promote safe storage and disposal of opioids and all medications. The AMA document indicates physicians and other providers need to:

- educate patients about safe use of prescription opioids;
- remind patients to store medications out of children's reach in a safe place; and
- talk to patients about the most appropriate way to dispose of expired, unwanted, and unused medications.

The AMA resource document and additional information can be found at *www.ama-assn.org/opioids-disposal*. Options for disposing of medications safely are available in the Initiatives section of the NABP website at *www.nabp.pharmacy* under AWAR^XE[®].

CDC Guide Shows Importance of Physicians, Pharmacists Working Together

Collaborative care by at least two practitioners working together with the patient to accomplish shared goals has been shown to improve hypertension control and cholesterol management, especially when the team involves a physician or nurse and a pharmacist, notes a new guide developed by the Centers for Disease Control and Prevention (CDC) Division for Heart Disease and Stroke Prevention, in collaboration with the American Pharmacists Association and AMA. The guide, Creating Community-Clinical Linkages Between Community Pharmacists and Physicians, discusses the importance of community-clinical linkages specific to community pharmacists and physicians and provides a framework for how community pharmacists and physicians might

approach the development of a link to help patients. In addition, the guide provides examples of existing community-clinical linkages between community pharmacists and physicians and discusses common barriers to and potential solutions for creating community-clinical linkages. The guide is available at www.cdc.gov/dhdsp/pubs/docs/ccl-pharmacy-guide.pdf.

FIP Report Shows Value of Pharmacists' Role in Consumers' Self-Care

Support from pharmacists will assist consumers in better health maintenance and greater health system efficiency, indicates a recently released report from the International Pharmaceutical Federation (FIP). The report, *Pharmacy as a gateway to care: Helping people towards better health*, discusses the various factors involved in individual self-care and the evidence that pharmacists can increase value for those individuals through many opportunities because informed, engaged, and educated consumers will play a greater and critical role in caring for themselves. The definition of self-care this report adopts is that of the World Health Organization: "the ability of individuals, families and communities to promote health, prevent disease, and maintain health, and to cope with illness and disability with or without the support of a health care provider."

The report is available at www.fip.org/files/fip/publications/2017-04-Pharmacy-Gateway-Care.pdf.

FDA Restricts Use of Codeine and Tramadol Medicines in Children; Recommends Against Use in Breastfeeding Women

As of April 2017, Food and Drug Administration (FDA) is restricting the use of codeine and tramadol medicines in children. FDA is also recommending against the use of these medicines in breastfeeding mothers due to possible harm to their infants. Codeine and tramadol medicines carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in this age group. These medicines should also be limited in some older children. Single-ingredient codeine and all tramadol-containing products are FDA-approved only for use in adults.

As indicated in the FDA Drug Safety Communication available at www.fda.gov/DrugSafety/ucm549679.htm, FDA is requiring several changes to the labels of all prescription medicines containing these drugs. These new actions further limit the use of these medicines beyond their 2013 restriction of codeine use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids. FDA is now adding:

- A Contraindication to the drug labels of codeine and tramadol, alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years.
- A new Contraindication to the tramadol label, warning against its use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids.

- A new Warning to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.
- A strengthened Warning to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants.

FDA urges health care providers to report side effects involving codeine- and tramadol-containing medicines to the FDA MedWatch program at www.fda.gov/safety/medwatch.

AVMA Warns Pharmacists and Pet Owners About Xylitol Pharmaceutical Products

Pharmaceutical products containing xylitol may be dangerous and fatal to dogs, warns the American Veterinary Medical Association (AVMA). Xylitol stimulates an insulin release that can result in severe hypoglycemia and fatal liver damage. Pharmacists and pet owners need to be aware of and protect against xylitol toxicoses, indicates AVMA. FDA-approved gabapentin capsules and tablets do not contain xylitol, but the liquid form does. In addition, xylitol-containing media might be used in compounding products if the pharmacist is uninformed about not using it.

AVMA urges pharmacists to not use xylitol-containing products when compounding for canine patients and to contact the veterinarian if a prescribed product contains xylitol. The veterinarian may be unaware that this sweetener is in the product. AVMA also encourages pet owners and caretakers to verify with the pharmacist when picking up their dog's medication at a human pharmacy that the medication does not contain xylitol. Xylitol-containing peanut butter should not be used to help a dog take its medication.

For more information, visit atwork.avma.org/2017/05/30/eliminate-xylitol-from-canine-prescriptions.

CDC Publishes Guide to Help Pharmacists Initiate CPAs With Prescribers

CDC published a guide that provides pharmacists with information and resources to empower them to initiate collaborative practice agreements (CPAs) with collaborating prescribers. The guide, Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team, contains a sample CPA and sample language that can be customized by pharmacists and prescribers using their specific state laws to create a CPA. The guide includes an overview of state laws, including which states currently allow CPAs. The guide is available at www.cdc.gov/dhdsp/pubs/docs/CPA-Team-Based-Care.pdf.

DEA Releases New Edition of Drugs of Abuse Resource Guide

Drug Enforcement Administration (DEA) released the 2017 edition of *Drugs of Abuse, A DEA Resource Guide,* which serves as a resource on the most commonly abused and misused drugs in the US. The latest edition, which is an update to the 2015 publication, describes the consequences of drug use, a drug's effects on the body and mind, overdose potential, origin, legal status, and other key facts. It also includes the most current information on new and emerging trends in drug misuse and abuse, including fentanyl, other opioids, and synthetic drugs. The 2017 edition can be found at www.dea.gov/pr/multimedia-library/publications/drug_of_abuse.pdf.

DISCIPLINARY ACTIONS

PHARMACIST	LIC.#	SANCTION	DATE
David Robinson	14295	Suspended	8/07/2017
PHARMACY TECHNICIAN	REG. #	SANCTION	DATE
Ashley Glasgow	T19375	Suspended	8/10/2017
Jennifer Gurule	T00842	Revoked	8/16/2017
Adam Evans	T11604	Revoked	8/16/2017
Lakira Whitaker	T08517	Revoked	8/16/2017
Mary Kathleen Jones	T06581	Revoked	8/16/2017
Demetris Grant	T05870	Suspended	8/16/2017
Corey Caston	T18557	Suspended	8/16/2017
Sirron Richardson	T13890	Suspended	9/27/2017
Shaneek Pinkney	T07475	Suspended	10/12/2017
Kierstin Powers-Harvey	T16432	Revoked	10/18/2017
Destiny Cameron	T13562	Revoked	10/18/2017
Ginny Kolbe	T17287	Revoked	10/18/2017
Melinda Fink	T16671	Revoked	10/18/2017
ESTABLISHMENT	PERMIT#	SANCTION	DATE
Frankford Family Pharmacy	P06707	Suspended	9/25/2017

Legislation that PASSED in 2017 Brian Logan, Legislative Liaison

Bill Number	XFile Bill Number	Sponsor	Synopsis	Title	Effective
HB0584	SB0572	Delegate Young, K.	Authorizing a manufacturer of an investigational drug, biological product, or device to make available the investigational drug, biological product, or device to eligible patients; requiring a manufacturer of an investigational drug, biological product, or device to notify a specified patient and a specified health care provider of specified side effects or risks; requiring the Office of the Attorney General to develop an informed consent form that meets specified requirements; etc.	Investigational Drugs, Biological Products, and Devices - Right to Try Act	10/1/2017
HB0613	SB0363	Delegate Hettleman	Authorizing a pharmacist who meets the requirements of State Board of Pharmacy regulations to prescribe and dispense specified contraceptives; requiring the State Board of Pharmacy, on or before September 1, 2018, and in consultation with the State Board of Physicians, the State Board of Nursing, and specified stakeholders to adopt regulations establishing the conditions under which pharmacists may prescribe and dispense contraceptives; etc.	Pharmacists - Contraceptives - Prescribing and Dispensing	7/1/2017
HB0628	SB0517	Delegate Barron	Requiring the Secretary of Health and Mental Hygiene and the Office of Administrative Hearings, in consultation with stakeholders and other interested parties, to adopt regulations for the supervision of each board or commission that is composed of individuals participating in the occupation or profession regulated by the unit in order to prevent anticompetitive actions and to determine whether the actions further a clearly articulated State policy to displace competition; requiring the Office to establish a specified process; etc.	Secretaries of Principal Departments - Supervision and Review of Decisions and Actions by Units Within Departments	6/1/2017
HB1031	SB0815	Delegate Pena-Melnyk	Providing that a specified provision of law requiring an individual to be registered and approved by the State Board of Pharmacy as a pharmacy technician before performing delegated pharmacy acts does not apply to a specified pharmacy student currently completing the first year of a professional pharmacy education program and performs, under the direct supervision of a licensed pharmacist, delegated pharmacy acts in accordance with specified regulations; etc.	State Board of Pharmacy - Registered Pharmacy Technicians - Exemption for Pharmacy Students	10/1/2017
HB1273	SB0997	Delegate Cullison	Authorizing a pharmacist to substitute an interchangeable biological product for a prescribed product under specified circumstances; requiring a pharmacist or the pharmacist's designee, except under specified circumstances, to inform specified consumers of the availability of an interchangeable biological product and the approximate cost difference as compared to a specified drug; requiring the State Board of Pharmacy to maintain on its Web site a link to specified lists of biological products; etc.	Pharmacists - Substitution and Dispensing of Biological Products	10/1/2017
HB1432		Chair, Health and Government Operations Committee	Requiring health care providers to prescribe the lowest effective dose of an opioid and in a quantity no greater than the quantity needed for the expected duration of specified pain unless the opioid is prescribed to treat a specified disorder or specified pain; requiring the dosage, quantity, and duration of specified prescribed opioids to be based on an evidence-based clinical guideline for prescribing controlled dangerous substances; authorizing specified disciplinary action by health occupations boards; etc.	Health Care Providers - Prescription Opioids - Limits on Prescribing (The Prescriber Limits Act of 2017)	5/25/2017
SB0110		Senator Conway	Authorizing, notwithstanding any other provision of law, a licensed pharmacist to dispense antibiotic therapy prescribed to sexual partners of patients diagnosed with specified sexually transmitted infections without making a personal physical assessment.	Public Health - Expedited Partner Therapy - Trichomoniasis and Pharmacist Dispensing	10/1/2017

Maryland Pharmacists on the Front Lines

Kip Castner, MPS, Chief, Center for HIV/STI Integration and Capacity

Background

Maryland is in the midst of an opioid epidemic. There is abundant evidence – such as fatal and non-fatal overdoses, opioid-related emergency department visits, acute hepatitis C infections, and increases in heroin-related admissions to substance abuse treatment – that injection drug us is widespread in suburban and rural areas of the state. Persons who inject drugs in these areas lack access to sterile injection equipment, and are thus more likely to re-ruse and share syringes. Consequently, they are at high risk for acquiring HIV, which is passed easily through sharing injection drug equipment. Maryland wants to avoid an outbreak of HIV among persons who inject drugs in rural area similar to what occurred in Scott County, Indiana in 2015, when HIV spread rapidly among a small group of rural injection drug users, yielding 190 new HIV cases in a year. Maryland recently passed legislation enabling Syringe Services Programs to operate statewide, but it will be several months before new programs are launched. In the meantime, pharmacists are the first line of defense against Maryland experiencing a Scott County-style outbreak of HIV among persons who inject drugs, by making sterile injection drug equipment accessible to users.

The Board of Pharmacy renews its support for pharmacy sales of syringes without a prescription

The Board of Pharmacy and pharmacists across Maryland have played a key role in the response to the opioid epidemic by providing both education and naloxone. On February 15th, 2017, Kip Castner, Chief of the Center for HIV/STI Integration and Capacity at the Department of Health and Mental Hygiene, presented to the Board of Pharmacy. He requested their support in helping increase access to sterile syringes through pharmacy sales. This visit built on the Board's previous incredible work on Naloxone access in the pharmacy setting. The board was supportive, offering to run this article and post a FAQ on their website as part of their strategy to build pharmacist' awareness of their opportunity to further the public health aim of reducing HIV and Hepatitis C risks among users. While Maryland legislation that approved Syringe Services Programs came into effect in October of 2016, standing up programs takes time, and pharmacists across Maryland can help fill that critical gap between now and when your county has a program launch.

How Individual Pharmacists Can Help

The best way to help is to know – and practice – that you do not need to require a prescription when selling syringes. Studies have shown that even where there are no legal barriers preventing pharmacy sales of syringes to prevent disease, attempts by persons who inject drugs to purchase syringes without a prescription are frequently unsuccessful. This can be because information and education about the law is not widely understood, and this can also have to do with the stigma connected to injection drug use. The evidence is clear that syringe access helps prevent the spread of bloodborne disease and does not increase someone's likelihood of using.

Stigma and other factors means that many people who inject drugs are not connected to services. Therefore, helpful behaviors include: affirming someone's decision to acquire sterile needles; and asking open-ended questions about additional needs, that do not include judgment or assumptions about what the person's most pressing needs are. These simple behaviors can build trust and rapport and help the person become ready to connect to other services.

COMAR states that syringes may be sold without a prescription with an indication of need. On April 18, 2007, the Board of Pharmacy voted unanimously to approve that the prevention of disease is an acceptable indication of need. The Board affirmed this position on February 15, 2017. Therefore, in all circumstances that a pharmacist believes that the provision of syringes will reduce the spread of disease, they are acting in accordance with COMAR and the Maryland Board of Pharmacy.

Pharmacists can also support local Syringe Services Programs (SSP) by referring persons who inject drugs to them as well as sharing their wisdom about the population with SSP staff. Please read the FAQ for more information and look out for the web content that will be published in the coming months!

Andrew Bell is the Syringe Services Program Coordinator at the Maryland Department of Health and Mental Hygiene. He can be reached at <u>Andrew.Bell@maryland.gov</u>. If there is already an effort to launch a program in your county underway, he can connect you with the local health department or community based organization staff in charge of that effort.

FREQUENTLY ASKED QUESTIONS: Pharmacy Sales of Syringes without a Prescription

Kip Castner, MPS, Chief, Center for HIV/STI Integration and Capacity

Do patients need a prescription to buy syringes?

No. While some states have laws requiring prescriptions to purchase syringes, Maryland does not.¹

What does COMAR - the Code of Maryland Regulations - say about pharmacy sales of syringes?

According to the COMAR, "the sales of needles and syringes or other paraphernalia shall be made by the pharmacist only in good faith to patients showing proper identification and indication of need." On April 18, 2007, the Board of Pharmacy voted unanimously to approve that the prevention of disease is an acceptable indication of need. Therefore, in all circumstances that a pharmacist believes that the provision of syringes will reduce the spread of disease, they are acting in accordance with the Code of Maryland Regulations.

Does the Board of Pharmacy support pharmacists selling syringes without a prescription?

Yes. In 2007, the Board received the constituent question, "Does the prevention of transmission of disease constitute an acceptable indication of need for the sale of needles and syringes?" The Board answered "Yes", voting unanimously to approve the Practice Committee's response that the prevention of disease is an acceptable indication of need for the sale of needles and syringes.

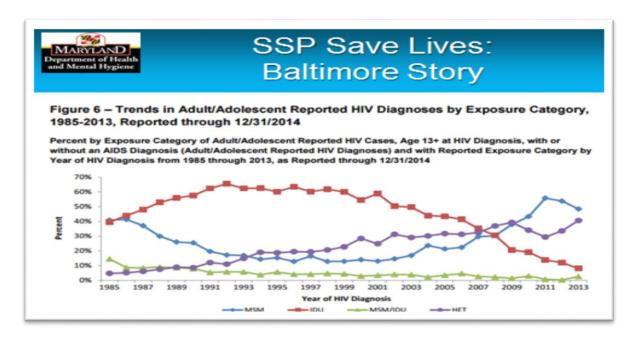
Who else supports pharmacy sales of syringes?

The American Public Health Association supports the provision of syringes to people who are injecting and are not ready to stop, it opposes laws in some states that require a prescription, and it "Urges medical training programs to educate their students about the importance of access to sterile syringes for injection drug users, including syringe prescription."

Similarly, the American Pharmacists Association supports the sale of sterile syringes and the revision of laws and regulations that provide barriers to doing so.⁴ Others include the American Medical Association and the Centers for Disease Control and Prevention.⁵

What impact does Syringe Access have on the risk of HIV transmission for Persons who Inject Drugs?

Access to injection drug equipment demonstrably reduces HIV infection among persons who inject drugs.



In 1994, Injection Drug Use (IDU) was Baltimore's leading mode of HIV transmission (65% of new cases.) The Baltimore City Health Department launched the Needle Exchange Project in 1994 and by 2013 new cases of HIV among IDU had fallen below 10%. As injection drug use increases statewide, Maryland is at risk of these gains being reversed.⁶

In 2015, Scott County Indiana, which previously averaged 4 new HIV diagnoses each year, had 190 cases in the worst outbreak ever in Indiana and one of the worst in the United States. Many other counties have similar sets of risk factor, including half the counties in West Virginia, some of which border counties in Western Maryland. But the counties in Western Maryland.

What are the risks of HCV transmission for Person Who Inject Drugs?

Injection Drug Use is the most significant risk factor in the transmission of HCV, estimated to be the cause of more than 50% of new infections. New HCV cases have risen significantly in recent years among those under 30 years old.

According to the CDC, there was a 365% increase in new HCV between 2006 and 2012.¹⁰ A study looking at four states, including West Virginia, attributed this rise to injection drug use in suburban and rural settings.

Why would a pharmacist sell syringes to someone without a prescription?

Providing someone with unused syringes reduces the likelihood that they will share their used syringes, satisfying the requirement laid out by the regulations. It gives people the opportunity to avoid the risks of HIV and HCV transmission associated with sharing used syringes. The research decisively shows the link between provision of sterile syringes and a reduction in syringe sharing.¹¹

What role do pharmacists have to play in the statewide expansion of Syringe Services Program?

Local stakeholder consultation, program design and procurement all take time. While SB97 authorized the establishment of Syringe Services Programs across the state, effective October 1, 2016, as of March 2017, no new programs are yet operating. This means that in all jurisdictions in the state except for Baltimore City, the only legal way to access syringes in through a pharmacy. Pharmacies, therefore, have a vital role in ensuring access to sterile injecting equipment, reducing the spread of HIV and HCV through the sharing of used syringes and to connecting people who use drugs to Syringe Services Programs as they launch.

Why shouldn't a pharmacist decide on a case-by-case basis whether to sell syringes to a customer seeking to purchase?

For two reasons: 1) this would place a undue burden on the pharmacist; and 2) because it can lead to disparities. Studies have shown that when pharmacist discretion was used, African Americans, Hispanics and men were significantly more likely to be refused than Caucasian women.¹² A study looking at attempts to purchase syringes in California looked at two counties where injection drug use was among the highest in the nation. Although a law had been passed to allow pharmacy sales of syringes, only 21% of attempts to purchase syringes at pharmacies were successful.¹³

Does providing syringes increase or encourage drug use?

No. Decades of scientific evidence have concluded that Syringe Services Programs do not cause any increase in drug use. In fact, many studies have demonstrated that Syringe Services Programs decrease drug use by connecting people who use drugs to treatment.¹⁴

What should a pharmacist ask someone who is purchasing syringes without a prescription?

As with any interactions with individuals who frequently face stigma, cultural competency and reading the specific interaction are of critical importance. There will be situations where someone's discomfort is clear and a reasonable goal for that initial interaction is to simply build trust, and no immediately offer a variety of referrals. If the individual seems open to questions, here are some that could helpfully be asked: Are you familiar with Naloxone, the drug used to interrupt an overdose? Are you interested in receiving training on how to use Naloxone? Are you interested in learning where you can get tested and treated for Hepatitis C and HIV?

How else have pharmacies supported Syringe Services Programs in other jurisdictions?

In upstate New York, a health-department-funded Syringe Services Program serving a nine-county area partnered with local pharmacies to provide vouchers to be redeemed for syringes. This was done to provide education and referrals to users, to provide an alternative source of sterile syringes in geographical locations that were underserved, and to build users' awareness of the program. Vouchers were distributed in outreach and testing settings. They were also available for pharmacists to provide directly to individuals that came in need of syringes. The vouchers were paid for by the Department of Health.

Who can I contact at the Department of Health if I have questions or I want to help improve syringe access in my county?

Andrew Ball, the Syringe Services Program Coordinator, at the Maryland Department of Health and Mental Hygiene, can be reached at Andrew.Ball@maryland.gov. If there is an effort to launch a program in your county, he can connect you with the local health department or community based organization staff in charge of that effort.

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The deadline for registering for PDMP through CRISP was July 1, 2017 so... if you have not yet registered, YOU'RE LATE!!!

Register at https://crisphealth.org/services/prescription-drug-monitoring-program-pdmp/pdmp-registration/

RECRUITMENT for Approved Drug Drop-Off Locations and Repositories throughout Maryland

Go to dhmh.maryland.gov/pharmacy/Pages/drug-repository.aspx and click onto the Maryland Prescription Drug Repository Program Application. Your pharmacy will be notified about approval.

REMINDER to Check and Update your Contact Information

Please check your contact information (e-mail address, residential address, name, employer) by completing and submitting the Name/Address/Employer change form at: dhmh.maryland.gov/pharmacy (see left column, under Online Services)

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Public Pharmacy Board meetings begin at 9:30am on the third Wednesday of each month and are open to the public. The Board encourages all interested parties to attend the monthly Board Meetings and awards 2 LIVE CEs to all licensees.

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